

**2478. Misbranding of natural estrogens. U. S. v. 175 Vials \* \* \*. (F. D. C. No. 23987. Sample No. 14205-K.)**

**LIBEL FILED:** December 10, 1947, Northern District of Illinois.

**ALLEGED SHIPMENT:** On or about June 27, 1947, by the Harrower Laboratory, from Glendale, Calif.

**PRODUCT:** 175 30-cc. vials of *natural estrogens* at Chicago, Ill.

**LABEL, IN PART:** "Plestrin in Oil Brand of Natural Estrogens in Oil."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the label statement "A concentrate of natural estrogens derived from gravid mares' urine, equivalent in terms of estrone to 10,000 I. U. per cc. (1.0 mg. crystalline estrone)" was false and misleading, since the article did not contain per cubic centimeter a concentrate of natural estrogens derived from gravid mares' urine equivalent in terms of estrone to 10,000 International Estrone Units or 1.0 milligram of crystalline estrone, but owed its apparent potency of approximately 9000 International Estrone Units in whole or in part to estrogens other than a concentrate of natural estrogens as they occur in and are extracted from the urine of gravid mares.

**DISPOSITION:** February 25, 1948. Default decree of condemnation and destruction.

**2479. Misbranding of Estradocreme, Nephrocrine, Androcrine, Orchicrine, and Io-Plexa-Dine. U. S. v. 14 Jars, etc. (F. D. C. No. 21321. Sample Nos. 48218-H to 48220-H, incl., 48222-H, 48226-H.)**

**LIBEL FILED:** October 31, 1946, District of Colorado; amended libel filed March 23, 1948, Northern District of California.

**ALLEGED SHIPMENT:** On or about May 31 and September 12, 23, 25, and 26, 1946, by the Woodard Laboratories, from Los Angeles, Calif.

**PRODUCT:** 14 jars, each containing 28½ grams, of *Estradocreme*, 11 cartons, each containing 90 tablets, of *Nephrocrine*, 5 bottles, each containing 30 cc., of *Androcrine*, 8 cartons, each containing 90 tablets, of *Orchicrine*, and 5 1-ounce bottles of *Io-Plexa-Dine*, at Denver, Colo., together with a number of booklets shipped in June 1946 entitled "Woodard Manual Formulae and Related Information."

Analysis disclosed that the *Estradocreme* was a perfumed cream containing an estrogen; that the *Nephrocrine* contained glandular material; that the *Androcrine* contained a ketosteroid such as an androgen, alcohol 78 percent, and a fatty substance; that the *Orchicrine* contained kelp, glandular material, and a manganese salt; and that the *Io-Plexa-Dine* contained glycerin, iodine, and a small proportion of a phenol.

**NATURE OF CHARGE:** *Estradocreme*. Misbranding, Section 502 (a), certain statements in the booklets were false and misleading, since they represented and suggested that the article when used as directed was effective to stimulate breast development and to increase the size of breasts. The article when used as directed was not effective for such purposes.

*Nephrocrine*. Misbranding, Section 502 (a), the designation "Nephrocrine" was misleading, since it suggested and implied that the article contained therapeutically useful constituents derived from kidney and one or more of the endocrine glands, whereas such was not the case; and the misleading impression of such designation was not corrected or nullified by the statement elsewhere upon the label "There are no scientific data available to indicate that the desiccated glandular substances in this product are physiologically or therapeutically active." Further misbranding, Section 502 (a), certain statements in the booklets were false and misleading, since they represented and suggested that the article was effective for the control of albuminuria and decreased permeability of the kidney glomerulus associated with nephritis and nephrosclerosis. The article was not effective for such purposes.

*Androcrine*. Misbranding, Section 502 (a), the designation of the article "Androcrine Inunction" and the statement on the labels "For the inunctionous administration of androgenic substance when indicated" were misleading, since they suggested and implied that the article supplied when administered in accordance with the directions in the labeling, namely, "Average Dose: Apply fifteen drops to the inner aspects of each thigh and the lower abdomen daily. Massage gently until liquid disappears," a therapeutically significant amount

of androgen, a substance elaborated by an endocrine gland, whereas the article when administered in accordance with the directions would not supply a therapeutically significant amount of androgen. Further misbranding, Section 502 (a), certain statements in the booklets were false and misleading, since they represented and suggested that the article was effective to modify or influence the male climacteric and was effective for conditions associated with androgenic deficiencies, whereas it was not effective for such purposes; and, Section 502 (e) (2), the article was fabricated from two or more ingredients and its label failed to bear a statement of the proportion of any alcohol contained therein, since the statement "Alcohol 95%" was not an accurate statement of the proportion of alcohol contained in the article.

*Orchicrine.* Misbranding, Section 502 (a), the designation "Orchicrine" was misleading, since it suggested and implied that the article contained therapeutically useful constituents derived from the orchic gland, an endocrine gland, whereas it did not contain such constituents; and the misleading impression of such designation was not corrected or nullified by the label statement "There are no scientific data available to indicate that the desiccated glandular substances contained in this product are physiologically or therapeutically active." Further misbranding, Section 502 (a), certain statements in the booklets were false and misleading, since they represented and suggested that the article was effective as supportive to androgen therapy in hypogonadism and in the male climacteric, whereas the article was not effective for such purposes.

*Io-Plexa-Dine.* Misbranding, Section 502 (a), the following statements in the booklets were false and misleading, since the article would exhibit effects similar to those of other iodine-containing substances, and it would not accomplish the therapeutic results stated and implied: "Io-Plexa-Dine can be administered for a long time in comparatively large doses without displaying the usual physiological manifestations of iodism \* \* \* Io-Plexa-Dine does not exhibit the usual toxic effects of iodine when taken internally \* \* \* A complete bodily saturation is thereby possible without any harmful effects \* \* \* Indications for use of Io-Plexa-Dine include \* \* \* thyrotoxicosis (Grave's Disease or hyperthyroidism). A number of cases of arthritis have also been reported as successfully controlled with Io-Plexa-Dine and some physicians claim complete cure for patients with advanced arthritic disease wherein large growths of osseous tissue and protuberances of the normal bone structure have been extensive. These areas of abnormal ossification have been completely eliminated. Some physicians have reported actual withdrawal of calcium from the arteries in arteriosclerosis. Its use is also indicated in cases of asthma and bronchitis. In stomach and intestinal conditions, Io-Plexa-Dine has been reported as being successfully used in the management of peptic and duodenal ulcers, amebic infection of the gut and in cases of extensive infection of the colon (colitis). As a topical application Io-Plexa-Dine is valuable as an antiseptic in otitis media (middle ear disease), and as a tonsil and throat spray for tonsillitis, pharyngitis and laryngitis \* \* \* As a dietary supplement for \* \* \* thyrotoxicosis (Grave's Disease or hyperthyroidism). Topically in otitis media; as a throat spray for tonsillitis, pharyngitis, laryngitis \* \* \* *Trichomonas vaginalis*. Experimental only—arthritis hypertrophic or osteo; arteriosclerosis \* \* \* systemic infections; pathologies attendant with fibrous exudation; tertiary syphilis; inoperable lymphadenitis; actinomycosis; pleurisy; pericarditis; chronic inflammatory conditions accompanied by a formation of fibroid connecting tissue, such as interstitial nephritis; locomotor ataxia; chronic rheumatism; lead poisoning or mercurial cachexia. Dosage: Chronic Pathologies; Begin with five drops after each meal and increase one drop daily until thirty drops are taken three times daily. \* \* \* Thyrotoxicosis: Start with five drops and gradually increase to fifteen drops three times daily."

**DISPOSITION:** Woodard Laboratories, Inc., appeared as claimant and filed a motion for removal of the case for trial in the Northern District of California, which motion was granted on December 19, 1946. The claimant withdrew its claim on June 4, 1948, and on June 18, 1948, a decree of condemnation and destruction was entered.